REMARKS

By the present response, Applicants have traversed the rejection of Claims 2 through 6. Claims 1-6 remain pending in the present application. Claims 1, 3, and 6 are independent claims.

The Examiner issued a Notice to Comply with the requirements for Amino Acid Sequence Disclosures in accordance with the provisions of 37 CFR § 1.821 through §1.825 with regard to the sequence listing appearing at page 3, 1st paragraph of the specification. By the present amendment, Applicant has deleted the last sentence of the third paragraph, which recites an amino acid sequence disclosed in U.S. Patent No. 5,431,034. Since the paragraph, as amended, no longer contains the listing of amino acids, no sequence identifier or separate paper and computer readable listings of the sequence are required. The remainder of the paragraph merely recites the name of the sequence (osteogenic growth polypeptide) and references the patent number disclosing the sequence. MPEP § 2422.03 provides that where prior art sequences are only referred to by name and a publication reference, they need not be included as a part of the "Sequence Listing" unless they are essential matter. The OGP sequence is not essential matter, but only presented for comparison purposes to distinguish the present invention from the prior art. No new matter has been added by the amendment. A copy of the Notice to Comply with the Sequence Listing requirements is attached hereto.

In the recent Office Action the Examiner rejected Claims 2-6 under 35 U.S.C. § 112, second paragraph, as being indefinite. The indication by the Examiner that Claim 1 is allowable over the prior art of record is noted with appreciation.

The Applicants respectfully traverse the rejection of Claims 2-6 under 35 U.S.C. § 112, second paragraph, as being indefinite. Reconsideration of the claims for the following reasons is respectfully requested.

In the Office Action, the Examiner maintains that in Claims 2-6 it is unclear what "effective amount" of SEQ ID NO: 2 (*sic*; the Claims recite SEQ ID NO: 1*)* would be required to carry out the method to enhance/promote the various therapeutic effects. The Examiner cites paragraph III of MPEP 2173.05(c), and notes that the specification only recites one test and one amount (2.5 to 5 mg/kg), suggesting that the claims be amended to recite the specific amount to render the claims definite.

Applicants respectfully submit that the only indication in the passage cited from the MPEP by the Examiner that the phrase "an effective amount" may be indefinite is the citation to *In re Fredericksen*, 213 F.2d 547, 102 USPQ 35 (CCPA 1954), which the MPEP characterizes as holding that "an effective amount" may be indefinite "when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or relevant art," and the rather open-ended reference to *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). Applicants submit that *In re Fredericksen* is inapposite, since the claims specify the function to be achieved.

Applicants further submit that *In re Mattison* is also inapposite. The claims in *Mattison* did not use the language "an effective amount." The invention in *Mattison* related to 2-hydroxybenzophenoxime compounds used as extractants for copper values from aqueous solutions at low pH. The disputed claim language was "to substantially increase the efficiency of the compound as a copper extractant." The Board held that "substantially" was not definite, since it was unclear how much of a percentage increase was substantial. The Board was reversed by the Court of Customs and Patent Appeals, which held the language sufficiently definite.

Nothing in the passage cited by the Examiner holds that a single example or a single range is insufficient to support the claims language "an effective amount." To the contrary, the passage cites *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), in which the Board held that the phrase "an effective amount" is definite, noting that "While some experimentation may be required to determine optimum dosages for these more potent prostacyclins in order to achieve a particular biological response, such experimentation is not considered to be undue." 12 USPQ2d at 1571. The Board further noted "We are satisfied that the skilled worker in this art could readily optimize effective dosages and administrative regimens for each of the recited utilities. As is well known, the specific dosage for a given patient under specific conditions and for a specific disease will routinely vary, but determination of the optimum amount in each case can readily be accomplished by simple routine procedures." *Ibid.*

The specification reports tests conducted on forty rabbits and reports that a range of 2.5 to 5 mg/kg was found satisfactory to achieve the functions claimed. As noted in *Skuballa*, the determination of optimal dosages and regimens for particular patients and particular diseases may be readily resolved by routine procedures carried out by those of ordinary skill in the art. No particularized reason has been cited by the Examiner why the general guidelines provided by the test reports reported in the specification do not provide sufficient guidance to determine an appropriate dosage and regimen for particular patients without undue experimentation for the particular functions claimed. Applicants submit that, while a single specific range is one way to claim the present invention, nevertheless, the phrase "an effective amount" is customary claims language and is reasonably definite in light of the specification, and is therefore also acceptable language for claiming the invention. Consequently, Claims 2-6 are sufficient to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention under 35 U.S.C. § 112, second paragraph, when the claims are read in light of the specification.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance. If such is not the case, the Examiner is requested to kindly contact the undersigned in an effort to satisfactorily conclude the prosecution of this application.

Respectfully submitted,

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RBL:dht
Attachments: Petition for One-Month Extension
Check in the Amount of $60.00

Application No. 10/577,739

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Peptide sequence on page 3 does not have SEQ ID NO: identifier

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For Patentin software help, call (703) 308-6856

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